IN THE UNITED STATES DISTRICT COURT

DISTRICT OF UTAH - CENTRAL DIVISION

UNITED STATES OF AMERICA, ex rel. EDYTH L. SIKKENGA, and EDYTH L. SIKKENGA, on her own behalf, Plaintiffs, vs. REGENCE BLUECROSS BLUESHIELD OF UTAH fka BLUE CROSS AND BLUE SHIELD OF UTAH, ASSOCIATED REGIONAL AND UNIVERSITY PATHOLOGISTS, INC., JOHN P. MITCHELL, JED H. PITCHER, FRANK BROWN, AND DOES 1–30, Defendants.	**MEMORANDUM DECISION AND ORDER** Case No.: 2:99-CV-00086 Judge Dee Benson

On February 12, 1999, Plaintiff Edyth Sikkenga filed this law suit on her own behalf and as relator in a False Claims Act case, 31 U.S.C. § 3729 *et seq*., pleading eight causes of action against Defendants Regence Bluecross Blueshield and Associated Regional and University Pathologists (ARUP). Defendants brought various motions to dismiss, arguing, inter alia, that Ms. Sikkenga had failed to plead fraud with that particularity required by the Federal Rules of Civil Procedure. All Ms. Sikkenga's claims were ultimately dismissed with prejudice and without reliance on Defendants' arguments regarding failure to plead fraud with particularity, and Ms. Sikkenga appealed. The Tenth Circuit Court of Appeals affirmed the dismissals of all but a single False Claims Act claim alleging that "ARUP submitted false diagnosis information on Medicare claim forms," and a pendent state law claim against Regence for wrongful termination,

and remanded the case to this Court. Sur-reply in Opposition, Dkt. No. 189, 1. The Court of Appeals explicitly—and repeatedly—noted that it was not ruling on the argument that the amended complaint did not plead fraud with the requisite degree of particularity. Acting on this perceived invitation from the Court of Appeals, both defendants have now moved the Court to dismiss Ms. Sikkenga's remaining claims for failing to plead fraud with particularity.[1]

An FCA case ordinarily involves an allegation that a particular claim made on the federal purse was false. And, at first blush, the amended complaint appears to adhere to this admirably straightforward pattern. Ms. Sikkenga alleges that ARUP and Regence manipulated the system whereby health care providers document the medical necessity of the services they provide, using a generic ICD-9-CM[2] diagnoses code, 796.4, signifying "other abnormal clinical findings," which

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[1]Both Defendants moved to dismiss Ms. Sikkenga's initial False Claims Act claims on Rule 9(b) grounds, and those motions were granted without prejudice. When Ms. Sikkenga filed an amended complaint January 25, 2002, only Regence included a 9(b) argument in its motion to dismiss. ARUP filed an answer February 22, 2002 and afterward a motion to dismiss for lack of subject matter jurisdiction. Ms. Sikkenga maintains that in answering the amended complaint ARUP waived any subsequent claim that the amended complaint failed to plead fraud with particularity. Ms. Sikkenga's argument fails for three reasons. First, the prior Tenth Circuit Court of Appeals opinion in this case contemplates Rule 9(b) scrutiny of Ms. Sikkenga's claims against ARUP: "We reiterate, in this respect as well [reversing the district court's dismissal of ARUP from the lawsuit], that we express no opinion of whether Sikkenga's allegations as to ARUP's allegedly false claims will survive scrutiny under Rule 9(b)." *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 722 n.30 (10th Cir. 2006). Second, while there is a split of authority on this issue, the majority position in that dispute appears to be that answering a complaint in a False Claims Act case does not preclude a defendant from later filing a motion to dismiss for failure to plead fraud with particularity. *See* John T. Boese, Civil False Claims and Qui Tam Actions, vol. 2 § 5.04 n. 180 (3d ed.) (2007). Finally, as a practical matter, Regence unquestionably moved to dismiss for failure to plead fraud with particularity and Ms. Sikkenga's case against Regence rests entirely on Regence's involvement with ARUP's alleged submission of false claims. Granting Regence's motion because Ms. Sikkenga has failed to plead ARUP's underlying alleged fraud with particularity necessarily includes a finding that the complaint is defective with respect to ARUP as well.

[2] "ICD-9-CM codes refers to the International Classification of Diseases, Ninth Revision, Clinical Modification codes, a coding system used to describe the diagnosis or medical condition

did not reflect the patients' true diagnoses. If the use of the generic ICD-9-CM code resulted in false claims, the patients involved presumably endured diagnoses that could not truthfully be described by the 796.4 code. Both Defendants appear to have believed this was the claim against which they were defending, and the amended complaint supplies ample support for that theory of Plaintiff's case: "ARUP started using the ICD-9-CM diagnosis code 796.4, 'other abnormal clinical findings,' in order to avoid having to obtain and provide accurate medical necessity documentation and to induce the government to pay ARUP's claims by reporting a false diagnosis. The use of this 'catch-all,' non-specific code . . . was false." Amended Complaint ¶ 47.

But when Defendants pointed out in the opening briefs in support of their motions to dismiss that Ms. Sikkenga had failed to plead that any one of the many, many claims she identifies as false in the amended complaint was actually false in this sense, i.e. that the 796.4 code did not represent the true diagnosis of any particular patient, Ms. Sikkenga disclaimed any intention of alleging this type of false claim.[3] Instead, in her opposition brief, Ms. Sikkenga shifted the ground of her attack from allegations of using false diagnostic codes to obtain payment for tests that were not medically necessary to a theory of false certification. Under this

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for which medical services are rendered when Medicare claims are submitted to Medicare carriers." *Sikkenga*, 472 F.3d at 709, n.8.

[3]Her protests to the contrary notwithstanding, Ms. Sikkenga's first brief in opposition to Defendants' most recent motion to dismiss continues to advance this theory of the case. *See, e.g.* Memo. in Opposition, Dkt. No. 181, 3 ("ARUP did not satisfy . . . preconditions for payment from Medicare, but by misrepresenting patients' diagnoses, obtained payment anyway."); *see also id*. at 4, 5 ("In particular, the Amended Complaint alleges that ARUP gave the diagnosis code 796.4 as the patients' diagnoses when 796.4 was not the patients' true diagnoses."; "Knowingly using a false diagnosis code like this to get Medicare claims paid is not a 'mere documentation deficienc[y].'")

theory, each use of the 796.4 code constitutes a false claim because the general code is inadequate to document properly the medical necessity of any test performed. Ms. Sikkenga relies primarily on *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001), for two formulations of this false certification theory, both of which she claims support the viability of her amended complaint. *Mikes* recognizes both express and implied false certification as a basis for liability under the False Claims Act. An express false certification is "a claim that falsely certifies compliance with *a particular* statute or contractual term, where compliance is a prerequisite to payment." *Mikes*, 274 F.3d at 698 (emphasis added). Even if there is no express certification of compliance, there can be an implied false certification where "the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." *Id*. at 699. Implied certification does not create liability under the False Claims Act for any and all failures in regulatory compliance: "the False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations." *Id*. A claim for implied certification still requires that the underlying rule or regulation claimed to have been violated *expressly* make compliance a precondition to payment. *See id*. at 700.

Having (at last) identified her claim as one for some form of false certification, Ms. Sikkenga must identify a statute, regulation, or contractual term that she claims Defendants violated and that expressly makes compliance a prerequisite for payment. In her opposition to Defendants' motion to dismiss, Ms. Sikkenga points to one regulatory and two statutory provisions she claims are prerequisites to payment and which use of the 796.4 code violated. Ms. Sikkenga begins with a quotation from 42 U.S.C. § 1320c-5(a), which requires health care providers of various sorts "to assure" that the services for which they bill the government "will be

supported by evidence of medical necessity." 42 U.S.C. § 1320c-5(a)(3). To begin with, Ms. Sikkenga explicitly equates a requirement "to assure" something with a requirement to certify something. *See* Memo. in Opposition at 6, n.3. Since she is attempting to salvage her theory of her case for false certification with a statute that speaks of assuring rather than certifying, it would be as well to provide some authority for the proposition that assuring is the same thing as certifying. Ms. Sikkenga has offered no authority for this equivalence. Both the implied and the express theories of false certification require that the duty to certify be express in the statute alleged to have been violated. The Court cannot accept as a basis for a false certification claim a statute that does not expressly impose a duty to certify in the absence of any evidence or argument concerning the claimed equivalence of assurance and certification.

But even if assuring were the same thing as certifying, the subsection on which Ms. Sikkenga relies does not preclude the use of the 796.4 code. Ms. Sikkenga quotes only a portion of the subsection on which she relies: health care providers must assure that their claims "will be supported by evidence of medical necessity." 42 U.S.C. § 1320c-5(a)(3). There is sound good sense behind this abridgment, for the subsection does not specify that evidence of medical necessity must be submitted at the time each claim for payment is made or that only the most specific diagnostic code available can serve as evidence of medical necessity, but rather that claims on the government

> will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities.

42 U.S.C. § 1320c-5(a)(3). There is nothing in the language of this subsection—or in the record as a whole—to suggest that a reviewing peer review organization has or would disapprove

ARUP's use of the 796.4 code. Moreover, the very case on which Ms. Sikkenga relies for her formulation of express and implied false certification holds that "the Medicare statute does not explicitly condition payment upon compliance with § 1320c-5(a)." *Mikes*, 274 F.3d at 701 (rejecting a claim of implied false certification based on 42 U.S.C. § 1320c-5(a)(3)) . In rejecting what is also Ms. Sikkenga's interpretation of this statute, the *Mikes* court observed that the section sets out requirements for participating in the Medicare program rather than prerequisites to payment, that the act elsewhere provides a mechanism permitting peer review organizations to monitor compliance with those conditions, and a system for imposing sanctions for violations. *See Mikes*, 274 F.3d at 702. In order to save Ms. Sikkenga's theory of false certification, § 1320c-5(a)(3) would have to condition payment on compliance with its terms and make use of the 976.4 code non-compliance. The subsection does neither.

The other two authorities Ms. Sikkenga proposes in her opposition brief provide no more support for her theory. The first, 42 U.S.C. § 1395u(p), requires physicians and practitioners to furnish appropriate diagnosis codes. Since ARUP is neither a physician nor a practitioner as defined by the statute, this passage is inapplicable to these defendants. The regulation Ms. Sikkenga cites in support of her position, 42 C.F.R. § 424.32, mandates that claims for "physician services, clinical psychologist services, or clinical social worker services must include appropriate diagnostic coding for those services using ICD-9-CM." ARUP does not provide the relevant services, a point the Tenth Circuit Court of Appeals made in Ms. Sikkenga's appeal to that court. *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 708 n. 8 (10th Cir. 2006) ("Such [ICD-9-CM] codes are not required from independent clinical laboratories for non-physician services, but can be used by them to document medical services.

See 42 C.F.R.§§ 424.3, 424.32.") Ms. Sikkenga's argument on this point has already been rejected in this very case in a decision binding on this Court; if Ms. Sikkenga believes the Tenth Circuit Court of Appeals to have been in error, this Court would venture to suggest that the United States Supreme Court is the appropriate forum in which to advance her argument in rebuttal.

While Ms. Sikkenga defended her position in oral argument on Defendants' motion to dismiss, she appears to have abandoned it in her sur-reply, where she introduces several new possible sources of a requirement to employ the most precise diagnostic codes available. This time around, Ms. Sikkenga relies chiefly on the HCFA 1500 form on which ARUP's claims were submitted.[4] The HCFA form does make several certifications preconditions for receiving payment, but none of those certifications are relevant to Ms. Sikkenga's case. The HCFA 1500 requires certification that services billed are medically necessary, but Ms. Sikkenga has made it abundantly clear that her claim does not relate to the medical necessity of the services ARUP performed, so this certification is irrelevant. Box 31 on the front page of HCFA 1500 contains a certification "that the statements on the reverse apply to this bill." Turning to the reverse of the form, Ms. Sikkenga points out two notices:

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[4]Ms. Sikkenga also cites 42 C.F.R. §§ 424.5(a)(5) & (6) and § 424.32(a)(1) in her sur-reply in support of her false certification argument. The first and last of these regulation set out the proper procedure for submitting claims but do not impose any requirement of submitting any particular content. They certainly do not require laboratories such as ARUP to submit the most specific ICD-9-CM code possible. The other regulation does speak to the content of a claim, but only in the most general terms, requiring that the claim provide "sufficient information" to determine if the claim is payable by Medicare. 42 C.F.R. § 424.5(a)(6). Like the other regulations, this one does not impose a particular content requirement. Since laboratories like ARUP are not required to submit ICD-9-CM codes at all, it is difficult to see that this regulation could implicitly require ARUP not only to supply an ICD-9-CM code but the most specific one possible.

> NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.
> NOTICE: Any one who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.

None of these passages adds much to Ms. Sikkenga's claim that ARUP's use of a generic diagnostic code constitutes a false certification. To begin with, the HCFA 1500 form certifies the statements on the reverse of the form apply to the bill; the box in which diagnostic codes are entered is on the front of the form. The notices on which Ms. Sikkenga now relies appear to be just that: notices. Warning a signatory to a document of the possible consequences of false statements is not the same thing as requiring the signatory to certify that the statements are true.

As the Tenth Circuit Court of Appeals observed in this case, the sine qua non of a false claims act case is a false claim: "Liability under the [False Claims Act] requires a false claim." *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 727 (10th Cir. 2006). Despite an undoubtedly genuine conviction that something somewhere is just not right about any and all claims ARUP submitted with the 796.4 code, Ms. Sikkenga never succeeds in articulating a legal theory that explains why any particular claim is false in any relevant sense.

What is at the bottom of Ms. Sikkenga's difficulties is her inability to decide what false means. She repeatedly asserts her belief that claimants on the Medicare purse must fill out forms with "true, accurate and complete information." Surreply at 2, Dkt. No. 189. The difficulty is that "true, accurate and complete" are three different concepts. "True" has to do with a correspondence with a verifiable external reality. Ms Sikkenga seems to be employing this definition of truth when she complains that the 796.4 code did not correspond to patients' actual

diagnoses. At other points Ms. Sikkenga seems to believe that a false claim is one that does not provide sufficient or sufficiently precise information. Both these ideas appear to be captured by Ms. Sikkenga's complaints that the 796.4 code is incapable of providing sufficient information and that all claims documented with it are therefore false. There are a variety of difficulties with the manner in which Ms. Sikkenga deploys these definitions, and each difficulty is fatal to her claims. First, Ms. Sikkenga has been unable to show that any of the claims listed in her amended complaint were false in the sense that the 796.4 was not any particular patient's "true" diagnosis. Neither has Ms. Sikkenga shown that her notion of completeness is embodied in any statute or regulation to which ARUP and Regence were subject. In other words, it was only a false claim to submit the amount of information ARUP did on each claim if ARUP were somewhere required to submit more information. Despite her progress through the United States Code, the Code of Federal Regulations, and the odd form, Ms. Sikkenga has been unable to locate any such requirement. Finally, Ms. Sikkenga appears to equate accuracy with precision. But this is not always appropriate. A properly calibrated scale that weighs to the nearest hundred pounds will produce accurate measurements of weight. Those measurements will not be terribly precise, but they remain nevertheless accurate. Likewise, the 796.4 code may not be the most precise one imaginable, but that is not necessarily the same thing as inaccuracy.

Lacking any evidence that any of the claims listed in her complaint were false at all, much less false in a way that matters for a False Claims Act case, Ms. Sikkenga is reduced by the end of her final brief to postulating doomsday scenarios that might one day materialize as a result of procedures like those employed by the defendants:

> The consequences of this practice of knowingly putting false diagnosis information on the Medicare claim form in order for the claim to circumvent the

> statutorily required review and audit procedures are catastrophic. Illustrative of this is what happens when ARUP submits claims to the Carrier for tests referred from hospitals. This violates Medicare regulations because, when a reference laboratory submits a claim for such tests to the Carrier, the claim is either excluded from Medicare coverage or results in a double billing, one from the referring hospital and one from the reference laboratory. This scenario, when coupled with Regence's assistance in circumventing the review and audit procedures, fraudulently covers up these double billed claims or claims for excluded services.

Sur-reply, Dkt. No. 189, 8–9. Ms. Sikkenga is careful not to accuse Defendants of doing anything of the sort, though:

> In expressing this observation, Sikkenga is *not* suggesting that the Court or Defendants view her Amended Complaint as an attempt to state a claim for double billing, but is only illustrating the seriousness and weight of ARUP's misrepresentation that Defendants suggest are "mere regulatory deficiencies."

Sur-reply, Dkt. No. 189, 9 (emphasis in original). In the end, Ms. Sikkenga is willing to dispense with the requirement that a claim be false in any sense at all. In Ms. Sikkenga's final formulation, this Court should permit her claim to proceed because it is possible to imagine circumstances (admittedly not present in this case) in which Defendants' documentation practices could have untoward results.

Philosophers, poets, and theologians have debated the meaning of truth and falsity in a venerable and valuable conversation for quite some time now. But the law cannot afford quite so much latitude. The False Claims Act, coupled with Rule 9(b), requires claimants to identify claims that are, in some sense that matters under a relevant statute, regulation, or contract, false. When pressed on what is false about Defendants' use of the 796.4 code, Ms. Sikkenga has embarked on a haphazard tour of (largely inapposite) statutes, regulations, and forms. Each time the rule on which she is resting proves an inadequate foundation for her argument, she alights,

however briefly, on another rule and then yet another, only to ask the Court in the end to abandon formal legal requirements altogether and go with her hunch. Ms. Sikkenga's theories, if adopted, would convert the federal courts into examiners of every aspect of regulatory compliance by any entity paid from Medicare funds because it is possible to imagine undesirable results from (alleged) noncompliance. Because courts lack the institutional competence to oversee the minutiae of compliance with Medicare regulations and because life does not last forever—nor would the Court wish it to under the conditions Ms. Sikkenga's theories of liability would create—it is as well that neither express nor implied certification would permit Ms. Sikkenga's amended complaint to survive Rule 9(b) scrutiny.

The Court finds some irony in the similarities (and differences) that exist between her amended complaint in this case and the diagnostic code about which she so vigorously complains. They both share the characteristic of not fully explaining the underlying information upon which they rest. Diagnostic code 796.4, "other abnormal clinical findings," does not on its face explain the precise nature of the underlying information. Neither does Ms. Sikkenga's amended complaint. Unfortunately for Ms. Sikkenga, while such generality is clearly allowed in the world of medicare claims it is clearly not allowed in the world of fraud litigation.

Ms. Sikkenga has had every opportunity to identify a single false claim or to find a provision in a statute, regulation, or contract that would support her generalized allegations of falsity. Having failed to do so, it would be futile to allow her to amend her complaint again. Ms. Sikkenga has failed to plead fraud with the particularity required by Rule 9(b) of the Federal Rules of Civil Procedure and Defendants' motion to dismiss the amended complaint is accordingly granted with prejudice. The Court also declines to exercise supplemental jurisdiction

over her state law claim, which is dismissed without prejudice. *See* 28 U.S.C. § 1367.

It is so ordered.

DATED this 11th day of September, 2007.

Dee Benson
United States District Judge